In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 15, 2020

ANA SEVERINO,	*	UNPUBLISHED
Petitioner,	*	No. 18-09V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Tetanus-diphtheria-pertussis ("Tdap"); Shoulder Injury Related to Vaccine Administration ("SIRVA"); Prior Finding of Facts; Entitlement.
Respondent.	*	

Shealene P. Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner.
Lisa A. Watts, Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On January 2, 2018, Ana Severino ("petitioner") filed a petition under the National Vaccine Injury Compensation Program (the "Vaccine Act" or the "Vaccine Program").[2] Petitioner alleges that she received a tetanus-diphtheria-pertussis ("Tdap") vaccine on January 20, 2015, which was the actual cause of her developing a Shoulder Injury Related to Vaccine Administration ("SIRVA"). Petition at Preamble (ECF No. 1).

On December 4, 2019, a fact hearing was held via videoconference to determine onset of petitioner's pain in her left shoulder and if her injury continued for a period of six months or more, as required by the Vaccine Act. Hearing Order (ECF No. 26); Transcript (ECF No. 31). On January 24, 2020, the undersigned issued a Finding of Fact Ruling. Findings of Fact (ECF No. 33).

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[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. §3501 note (2012), **because this ruling contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the ruling is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the ruling will be posted on the court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

For the reasons, consistent with the prior Finding of Fact and respondent's amended Rule 4c Report, the undersigned finds that the petitioner is entitled to compensation.

I. Procedural History

Petitioner filed her petition on January 2, 2018, alleging that she sustained a left shoulder injury caused by the tetanus-diphtheria-pertussis ("Tdap") vaccine administered to her on January 20, 2015. Petition at Preamble. On December 21, 2018, respondent filed his Rule 4(c) Report, stating that the records had been reviewed by medical personnel of the Department of Health and Human Services, Division of Injury Compensation Programs, and concluded that the case was not appropriate for compensation. Respondent's Report ("Resp. Rept.") at 1-2. (ECF No. 15). In the report, respondent stated that petitioner's claim does not meet the Table criteria for SIRVA. Resp. Rept. At 4. Respondent stated that the contemporaneous medical records did not establish onset within 48 hours of vaccine administration, as required for a Table SIRVA injury. *Id.* Additionally, respondent stated that there was no evidence that petitioner's reaction persisted for more than six months, as required by the Vaccine Act. *See* §300aa-11(c)(1)(D). A

A fact hearing was held in December 4, 2019, after which the undersigned made a factual finding regarding the onset of petitioner's shoulder injury. Finding of Facts (ECF No. 33). The earlier procedural history was set forth in the Finding of Facts Ruling and will not be repeated here. Finding of Fact, issued on January 24, 2020. After the undersigned issued the Finding of Facts, the undersigned ordered petitioner to forward a demand for settlement to respondent and file a status report indicating completion. *Id.* at 10.

On April 9, 2020, respondent filed an amended Rule 4(c) report, stating, "Based on the Special Master's fact ruling, and medical record evidence submitted in this case, DICP will not continue to contest that petitioner suffered SIRVA as defined by the Vaccine Injury Table." Respondent ("Resp.") Amended Rule 4c Report ("Am. Rept.") at 6. Respondent recommended that the Special Master decide the issue of entitlement in the above-captioned case based on the record as it stands now. *Id.*

II. Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves,

inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

The Vaccine Act provides two avenues for petitioners to receive compensation. A petitioner may demonstrate either that she suffered a "Table" injury,[3] or that she suffered a different injury which was caused-in-fact by a vaccine listed on the Vaccine Injury Table. In this case, petitioner is alleging she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA"), which is a Table Injury. The Table provides that The Vaccine Table's Qualification and Aids to Interpretation ("QAI") provides:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would

[3] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 U.S.C. § 100.3, corresponding to the vaccine received within the time-frame specified.

> not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Discussion and Conclusion

Respondent does not dispute that petitioner received the vaccination at issue intramuscularly in her left deltoid on January 20, 2017. Instead, respondent argued that the onset of petitioner's pain did not occur within 48 hours after receipt of the vaccination and that petitioner did not establish that her alleged injury lasted for six-months or longer. *See* Resp. Rept. at 4-5.

The undersigned resolved both factual issues in the Finding of Fact ruling issued on January 24, 2020, in which the undersigned found that petitioner's onset of pain occurred within forty-eight hours of receipt of the Tdap vaccine administered on January 20, 2015 and that petitioner demonstrated that her injury lasted for more than six months after vaccine administration. Finding of Fact at 8-9.

The Finding of Fact includes of review of petitioner's medical records, the affidavits provided by petitioner and the testimony provided by herself, a work colleague and her husband. *See* Finding of Facts at 3-8. Those summaries will not be repeated here but are incorporated herein by references. Additionally, that Ruling is incorporated herein by references as if fully set forth.

In respondent's amended Rule 4(c) Report, he stated that "petitioner has otherwise satisfied the criteria set forth in the Vaccine Injury Table and the Qualifications and Aids to Interpretation ("QAI") for SIRVA." Resp. Am. Rept. at 3; *see also* 42 C.F.R. §§ 100.3(a)(I-II) and (c)(1)).

Based on the record as a whole, including the testimony of petitioner and her witnesses, petitioner's medical records, and respondent's amended Rule 4(c) report, the undersigned finds that petitioner has established a Table SIRVA injury resulting from her January 20, 2017 Tdap vaccination. Thus, petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master